## REMARKS

The foregoing amendment is submitted to more clearly set forth the claimed invention and to highlight the differences between the claimed invention and the cited prior art. Claim 1 has been amended to limit the calcium-containing compounds to those that are non-water soluble or sparingly water soluble. Support for this amendment can be found in claim 13 which has now been canceled. This amendment has resulted in a revision of claims 14 and 30 to emphasize that the preferred compound is calcium carbonate. In addition, claim 1 has been amended to indicate that a reasonable number of pieces of the chewing gum needed to provide an effective amount of the calcium containing compound is 3 to 5 pieces. Support for this amendment can be found in original claim 16 which has now been canceled. Similar amendments have been made to claim 19 resulting in the cancellation of claims 29 and 32. The remaining changes to the claims are submitted to place the claims in better form. It is therefore submitted that the present amendment is fully supported in the application as filed and entry thereof is deemed proper and is respectfully requested.

The claims of the application (claims 1-16 and 18-32) have been rejected under 35 USC Section 112 for indefiniteness because it is not known what is intended by "a reasonable number" of pieces of the chewing gum and "the minimum daily nutritional amount of calcium". The rejection is hereby traversed and reconsideration is respectfully requested.

The issue regarding "a reasonable number" has been addressed by identifying a reasonable number of pieces of chewing gum as specifically identified in the application as filed. The reasonable number is 3 to 5 pieces of the chewing gum composition per day. It will be understood that the quantitative term "3 to 5" is being submitted not to limit the invention to this number of pieces of chewing gum composition per day but to further define the term "reasonable number" as supported in the application as filed.

The claims of the application retain the phrase "the minimum daily nutritional amount of calcium". First, it is respectfully submitted that this term is known in the art and/or readily ascertainable by those persons skilled in the art. It is common place, if not required, to provide on typical packaging for multi-vitamins and minerals (including calcium) the minimum daily nutritional requirements of each of the vitamins and minerals contained therein. Thus, the minimum daily nutritional amount of calcium is known, although the amount can vary depending on a variety of factors including body weight and gender (see page 5 of the present application). However, one of ordinary skill in the art can readily determine the amount by looking at the packaging for multi-vitamin and mineral products. If the Examiner wishes, Applicants are prepared to provide copies of such packaging for this purpose. It is therefore submitted that the phrase "the minimum daily nutritional amount of calcium" has a clear meaning in the art and would be understood by those of ordinary skill in the art.

Applicants have amended claims 1, 9, 19 and 25 as requested by the Examiner in paragraph 3 of the Office Action. It is therefore submitted that all informalities in the claims have been addressed.

Claims 1, 2 and 13-15 stand rejected as anticipated by Bell et al. (WO 00/06127). In addition, claims 4-9, 11, 16, 18, 19, 21-25, 27 and 29-33 have been rejected as obvious over Bell et al. The rejections are hereby traversed and reconsideration is respectfully requested.

Before discussing the Bell et al. reference, a brief discussion of the present invention and particularly the problems incurred in attempting to provide a chewing gum composition which can deliver, within a reasonable number of pieces of the chewing gum composition, an effective amount of calcium is presented below. For chewing gum to be a viable delivery vehicle for calcium supplementation, the present invention has taken into consideration the amount of calcium that is needed for supplementation, how it must be delivered and how to incorporate the requisite amount in a chewing gum as a delivery vehicle. The present invention provides that the chewing gum needs a centerfill portion in which a uniformly dispersed and stably suspended calcium-containing compound (now limited to non-water soluble and sparingly water soluble forms of calcium) is distributed therein. Furthermore, it has been observed that calcium can become entrapped in the non-water soluble gum bolus of conventional gums. Accordingly, the present invention specifically provides for the placement of the calcium in the centerfill portion of the gum which does not contain a gum base capable of entrapping the calcium and preventing its release.

One of the problems associated with employing chewing gum as a delivery vehicle is that those who chew gum will typically chew only a reasonable number of pieces of chewing gum during the course of the day. Even if it can be determined that calcium can be incorporated into a chewing gum, unless an effective amount of calcium can be delivered to the user in a reasonable number of pieces of chewing gum per day, the gum cannot realistically serve as a vehicle for delivering calcium. Therefore, determining how to provide calcium in an effective amount by chewing a reasonable number of pieces of chewing per day is critical to providing a chewing gum for this purpose. We have already discussed what is meant by a reasonable number of chewing gum pieces per day and while that number may vary among users, a guideline has been provided in claim 1 that a reasonable number can be considered from three to five pieces per day.

In addition to providing an effective amount of calcium, the organoleptic properties of the chewing gum must not be compromised. If the chewing gum is loaded with calcium in order to deliver an effective amount within a reasonable number of pieces, the gum will take on a gritty and therefore undesirable feel. A gum of this type will not be accepted by the public and will not be useful for the delivery of the requisite amount of calcium. Therefore, in order to provide an effective amount of calcium without altering the organoleptic properties of the chewing gum, it is necessary to place the calcium in the centerfill portion of the chewing gum in a uniformly dispersed and stably suspended form of small particle size calcium. In this manner, a sufficient amount of the calcium can be delivered

without loss of desirable organoleptic properties. In this regard, attention is directed to claims 7-12 of the application in which preferred ranges of particle sizes are presented. Generally, the particle sizes of calcium set forth in these claims are lower than typical particle sizes associated with calcium-containing compounds. By limiting the particle size to the preferred ranges set forth herein, uniform distribution and stable suspension of the calcium can be enhanced.

Referring to the Office Action, Bell et al. (WO 00/06127) is the principle reference cited against the claims of the application. In this regard, the Office Action refers to the comments made in the Office Action of May 18, 2004 wherein it is stated that Bell et al. discloses a centerfill chewing gum composition including a shell portion and a centerfill with the centerfill including a mixture of neutraceuticals which can include calcium gluconate and a botanical. Also, a hydrocolloid may be present in the soft core which is alleged to be the equivalent of a suspending agent. The Office Action concludes that finding the optimum viscosity and the optimum calcium compound particle size would require nothing more than routine experimentation. The rejections based on Bell et al. are respectfully traversed and reconsideration is respectfully requested.

Bell et al. is principally concerned with the problem of delivering multiple neutraceuticals within a centerfill confectionery chewing gum composition. Certain neutraceuticals have poor taste or poor consistency or interact poorly with each other (page 2, first paragraph). Bell et al. addresses the problem by placing the incompatible neutraceuticals apart from each other (i.e. separately in the shell and in

the core). The Bell et al. invention provides for incorporating a neutraceutical in the core that advantageously is delivered rapidly to the gut while the neutraceutical incorporated in the shell is advantageously delivered slowly to the oral cavity (page 9, lines 10-13). Page 9, beginning at line 30 indicates that neutraceuticals contemplated for use in Bell et al. include botanicals, minerals and mineral salts. Minerals are stated to include zinc, calcium, iron and selenium. Mineral salts include the organic and inorganic salts of these minerals including gluconate, acetate, chloride and sulfate. The preferred mineral is zinc.

All of the salts provided as examples of the calcium mineral salts are more than sparingly soluble in water and therefore fall outside of the present claims. For example, calcium chloride, calcium acetate, calcium gluconate and calcium sulfate are all soluble in water. The present claims have been limited to the use of non-water soluble and sparingly water soluble forms of calcium and therefore do not embrace the particular salts disclosed in the reference. In addition, none of the examples of the reference show any calcium compounds, and particularly non-water soluble calcium compounds. Accordingly, the teaching of Bell et al. with respect to calcium compounds clearly favors compounds which have been excluded from the present claims because they are generally soluble in water. In contrast, the present claims are directed to non-water soluble and sparingly water soluble calcium compounds especially calcium carbonate. As indicated at page 3, beginning at line 10 of the present application, water soluble calcium compounds do not possess a sufficiently high calcium content to provide effective dosing of calcium.

As previously indicated, the present claims require the presence of the non-water soluble or sparingly water soluble calcium to be uniformly dispersed without settling within the centerfill portion of the chewing gum composition.

As indicated beginning at page 11, line 4, Bell et al. indicates that minerals are incorporated in an outer hard confectionery shell and botanicals are incorporated in the core encased by the outer shell. For chewing gums, the mineral is incorporated into the outer chewing gum shell while the botanical is incorporated in the core (page 11, lines 9-12). The examples are consistent with this teaching. Example 1 shows the presence of zinc in the shell as does Example 2. The botanical Echinacea is present in the core. Example 3 provides for caffeine in the gum shell and Ginseng in the core. Similar compositions are found in Examples 4 and 5. Thus Bell et al. teaches and supports the presence of minerals in the shell and does not disclose the presence of minerals in the core. There is no mention of placing minerals in the core nor any teaching of how to distribute minerals and particularly calcium so that an effective amount can be delivered from the centerfill portion. The delivery vehicle for minerals as taught by Bell et al. is the shell of a centerfill chewing gum product not the core.

Thus, the presence of a hydrocolloid within the centerfill portion does not teach one of ordinary skill in the art how to uniformly distribute and suspend calcium within the centerfill portion as required in the present claims. Furthermore, Bell et al. does not even teach the particular type of calcium compounds which need to placed into the centerfill portion in accordance with the present invention in order to provide

an effective amount of calcium with any reasonable number of chewing gum pieces per day.

Bell et al. does teach that hydrocolloids can be added to the centerfill portion. Hydrocolloids function as effective stabilizers due to their hydrophilicity and their ability to form colloidal dispersions. The majority of food hydrocolloids are either natural materials such as exudates or chemically modified or chemically synthesized materials. These materials differ greatly in their molecular structure, size and secondary molecular forces. Molecular structures include linear, single branch, substituted linear and branch-on-branch. There is a similar wide molecular weight range for hydrocolloids of from about 30,000 to 400,000,000. Furthermore, secondary molecular forces that need to be considered include the degree of hydrogen bonding, ionic interactions and the strength of van der Waals forces. Because of the immense variety of hydrocolloids, the formation of a stable suspension for non-water soluble and sparingly water soluble calcium compounds is not a routine exercise when the person of ordinary skill in art is only provided with a teaching that hydrocolloids can be put in the centerfill portion of the chewing gum composition. Because Bell et al. does not provide the requisite guidance to one of ordinary skill in the art to place minerals including calcium within a centerfill portion, there is no teaching or suggestion of what type of hydrocolloids may be useful for that purpose. This situation is magnified when the compounds that are to be placed in the centerfill portion in accordance with the present invention are a very specific class of calcium compounds and not the type of calcium compounds disclosed in the references. Indeed, as previously indicated, Bell et al. discloses placing minerals in

the shell and not the core. It therefore follows that one of ordinary skill in the art could not arrive at the claimed invention from what is fairly disclosed in Bell et al. To arrive at the claimed invention as suggested in the Office Action requires hindsight in the form of a thorough knowledge of the present invention. It is therefore submitted that the present claims are clearly patentable over Bell et al. alone or in combination with the other references cited in the Office Action.

More specifically, Friello et al. discloses the employment of a centerfill containing a glycerin dispersion containing up to about 6% by weight of a thickening agent which can include carboxymenthylcellulose, pectin, alginates and the like. The purpose of the glycerin is to provide a sweetening effect to the chewing gum composition and the thickening agent is intended to prevent an increase in the viscosity of the glycerin. There is no teaching or suggestion of employing the centerfill for delivery of a calcium-containing compound. Accordingly, Friello et al. does not cure the deficiencies of the Bell et al. reference as discussed above. The combination of Bell et al. and Friello et al. therefore is insufficient to render the present application obvious to one of ordinary skill in the art.

Glass et al. is cited for the same purpose and particularly that the hydrocolloid of Bell et al. can be a material that is specifically employed in the present application. However, like Friello et al. and Bell et al., Glass et al. does not teach or suggest the particular class of calcium-containing compounds uniformly distributed and stably suspended within the centerfill portion of the chewing gum to deliver an effective

amount of calcium to the user within a reasonable number of chewing gum pieces per day.

Finally, Cherukuri et al. discloses a coextruded chewing gum which includes an extruded center portion surrounded by and bonded to an extruded outer shell. The center portion of the coextruded chewing gum is formed of a modified gum base (i.e. the gum base does not include styrene-butadiene as described at column 2, line 45). As indicated in the present application beginning at page 5, line 24 if the calcium-containing calcium is bound up in the chewing gum composition then it cannot be released during the normal chewing cycle and as a consequence there is insufficient calcium for delivery to the oral cavity. Regardless of how much of the calcium-containing compound is provided to the gum base too little of the calcium-containing compound is released (present application beginning at page 6, line 15).

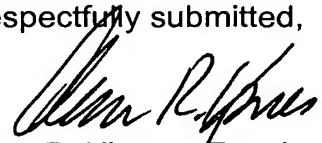
The purpose of using a non-styrene-butadiene gum base as taught in Cherukuri et al. is to provide a chewing gum composition with a very soft texture and one that can be readily handled with conventional gum wrapping machines (column 1, lines 6-11). The soft core gum base of the reference therefore will still retain calcium and therefore prevent the calcium from entering the oral cavity. Accordingly, any calcium which may be used as a filler-texturizing agent as described in Cherukuri et al. will not be available for release to provide an effective amount of calcium while chewing a reasonable number of pieces of chewing gum per day. Accordingly, it cannot be expected that if a calcium-containing compound is used as

a filler-texturing agent in the reference, that a meaningful amount of calcium can be delivered to the user.

It is therefore submitted that the present application is neither anticipated by nor rendered obvious over the references relied on in the Office Action. Applicants therefore submit that the present application is in condition for allowance and early passage to issue is therefore deemed proper and is respectfully requested.

It is believed that no fee is due in connection with this matter. However, if any additional fee is due, it should be charged to Deposit Account No. 23-0510.

Respectfully submitted,



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